

MANUFACTURING EXTENSION PARTNERSHIP

Success Stories from the Field

Quality Products of Montana

Montana Manufacturing Extension Center

Research "Marathon" Leads To Long Life Goods For Quality Products

Client Profile:

Quality Products, Inc., located in Missoula, Montana, manufactures a specialized dental office supply, the Marathon Sterilization Pouch, for maintaining the sterility of dental tools until they are ready for use. Its pouches hold dental equipment during and after the sterilization process in a special heating unit called an autoclave. The pouches meet and/or exceed complicated and changing regulations that guide the manufacture of medical devices. The company currently employs less than 20 people.

Situation:

Quality Products had several research and development (R&D) hurdles to overcome in the manufacture of the Marathon product, including shrinkage; writing testing standards during initial FDA certification because no existing comparative data was available; and several generations of changes on the machinery for full-scale manufacture and edge sealing on the pouches. One of the most significant hurdles was created during the 10-year development period, when more stringent regulatory standards for medical devices were mandated as a result of heightened worldwide concerns over the spread of pathogens. This greatly increased the number of sterilizations required in dental offices. While Quality Products' earlier designs were built to be reusable, a lubricant used on dental equipment was breaking down into solvents in the sterilization process; with increased reuse, it had begun reacting with the see-through film side of the bags. This reaction caused degradation, making the pouches invalid before FDA 510(K) testing had indicated. The company needed to develop a pouch able to stand up to a greater number of trips through the autoclave. Additionally, Quality Products discovered that European markets greatly favored a recyclable product, and challenged R&D to find a new, more durable, and recyclable polypropylene film. Identification of the solvent as the root cause of the "melting" took time and research, but the real obstacle became locating the highly specialized replacement material that would resist the solvent interaction and meet reusability and recycling standards the company had set for its product. Unable to find any materials to meet this criteria from known suppliers, the company called on the Montana Manufacturing Extension Center (MMEC), a NIST MEP network affiliate, for assistance.

Solution:

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MMEC initiated a search that led to the perfect material for longevity and successful testing of the product. MMEC produced a target list from which the company could begin negotiations for the correct composition at a competitive price. Ensuing conversations between Quality Products and plastics manufacturers netted just the right supplier and ended 10 years of searching for the perfect material. MMEC also assisted the company with vigilance procedures for handling customer feedback, failure mode analysis, and labeling needs.

Results:

Identified the perfect raw material needed for product manufacture.
Enabled the fledgling product to again meet/exceed FDA 510(K) standards.
Remained competitive in new market conditions.
Expecting \$150,000 in monthly sales over the next 18 months.

Testimonial:

"There would be no product today without finding this new film. I would never have found the source without the help from the Montana Manufacturing Extension Center. It was the savior of the project."

Larry Larson, Research & Development, Special Projects